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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,302	01/17/2002	Kyung Jin Kim	A-67640-2/RFT/NBC	6859
23552	7590	08/18/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			SKELDING, ZACHARY S	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 08/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/053,302	KIM ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-11, and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 12, 13, 15-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's response filed June 6, 2006 is acknowledged.

Claims 1-3, 5-11 and 14-23 are pending.

**Claims 9-11 and 14 objected to under 37 CFR 1.75(c)** as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim, moreover, claim 14 also does not refer back in the alternate only. See MPEP § 608.01(n).

**Accordingly, claims 9-11 and 14 have not been further treated on their merits and are therefore withdrawn.**

Thus, *claims 1-3, 5-8 and 15-23 are under examination* as they read on anti-IFNAR2 antibodies.

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.
3. The instant claims under examination appear to be entitled to the benefit of priority of USSN 60/061,185, filed **October 6, 1997**.
4. The rejections of record can be found in the previous Office Action, mailed March 21, 2006.

This Office Action is in response to Applicant's response filed June 6, 2006.

The previous rejections under **35 U.S.C. § 101, statutory type double patenting, and** under the judicially created doctrine of **obviousness-type double patenting (provisional)** have been withdrawn in view of the abandonment of USSN 08/943,771.

**New Grounds of Rejection** are set forth below.

5. Applicant is advised that should claim 19 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
6. It is noted that the instant specification discloses the apparent abbreviations "IGSF" and "IGSF-3", see for example, the paragraph bridging pages 3-4. From the context in which these terms are used they appear to have the same meaning; however, applicant is invited to clarify if this is indeed true.

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Moreover, it is noted that a similar term, "ISGF3", appears in the art which is an abbreviation for "IFN-stimulated gene factor 3" (see, for example Chuntharapai, et al. (J Immunol. 1999 Jul 15;163(2):766-73, citation C5 on applicants' substitute 1449A submitted January 13, 2003).

7. **Claim 23 is rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "block IGSF complex formation" in the instant claim is indefinite in that "IGSF complex" appears to be an arbitrary name for a biomolecular complex. While the name itself may provide some notion of the composition of this biomolecular complex, the use of this term is not sufficient to distinctly claim this biomolecular complex. Applicant should particularly point out and distinctly claim the "IGSF complex" by claiming sufficient characteristics associated with this complex (e.g. activity, molecular weight, etc.). Claiming a biomolecular complex by a particular name given to it by various workers in the field fails to distinctly claim the composition of the biomolecular complex.

Applicant is reminded that any amendment to the claims must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **Claims 1-3, 5-8 and 15-23 are rejected under 35 U.S.C. § 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

**A. ATCC Deposit: Claims 1-3, 5-8 and 15-23**

It is apparent that the hybridoma cell lines HB12426, HB12427 and HB12428 are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

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In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification at page 78 to recite the “ATCC Accession No.” and “Deposit Date” and the current name and address of the depository is required.

As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement *from a person in a position to corroborate the fact*, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

#### **B. Blocking vs. Non-blocking monoclonal antibodies: Claims 5-8 and 21-22**

The rejection that follows arises because the instant claims recite limitations inconsistent with the biological properties of the specific antibodies recited in claim 1 (from which the instant claims depend).

For the purposes of examination under 35 U.S.C. § 112, 1st paragraph, the instant claims, given their broadest reasonable interpretation consistent with the instant specification, encompass in their breadth monoclonal antibodies 3B7, 1F3 and 1D3, wherein:

- said monoclonal antibodies do not block binding activity of any Type I interferon (claims 5 and 8);
- said monoclonal antibodies do not block binding activity of IFN $\alpha$ -2/1 (claim 6);
- said monoclonal antibodies block anti-viral activity of any first Type I interferon but do not block anti-viral activity of any second Type I interferon (claim 7);
- said monoclonal antibodies block the anti-viral activity of various recited first Type I interferon but do not block anti-viral activity of any second Type I interferon (claim 21);
- said monoclonal antibodies block the anti-viral activity of various recited first Type I interferon but do not block anti-viral activity of IFN- $\beta$  (claim 22); and
- wherein “**block binding activity**”, “**block anti-viral activity**” and “**block IGSF complex formation**” encompass any blocking activity, i.e., from “weak” blocking to “strong” blocking.

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*At pages 69-71 of the instant specification, the biological characteristics of the 3B7, 1F3 and 1D3 monoclonal antibodies are disclosed as follows:*

**(1) monoclonal antibodies 3B7 and 1F3 block binding, anti-viral activity and IGSF complex formation for all the interferons tested in the instant specification, and**

**(2) monoclonal antibody 1D3 weakly blocks binding, anti-viral activity and IGSF complex formation for all the interferons tested in the instant specification,**

**EXCEPT monoclonal antibody 1D3 does not block IFN $\alpha$ -2/1 binding, or IFN $\beta$  anti-viral activity.**

It is noted that "all the interferons tested" include the particular interferons recited in claims 6, 21 and 22.

Thus, with respect monoclonal antibodies 3B7 and 1F3, the instant specification does **not** provide sufficient direction or guidance to enable one of skill in the art to make monoclonal antibodies 3B7 and 1F3 with the properties recited in the instant claims because these monoclonal antibodies ***block the binding, anti-viral activity and IGSF complex formation for all the interferons tested*** according to the instant specification.

With respect to monoclonal antibody 1D3, the instant specification does not provide sufficient direction or guidance to enable one of skill in the art to make a 1D3 monoclonal antibody which,

(a) does **not block** the binding activity of *any* Type I interferon (**claims 5 and 8**), or

(b) **blocks** anti-viral activity of *any* first Type I interferon...(claim 7),

because as described in the instant specification:

(a') monoclonal antibody 1D3 is a weak blocking monoclonal antibody for most of the interferons tested, and

(b') monoclonal antibody 1D3 does not block IFN $\beta$  anti-viral activity.

Moreover, the instant specification does not provide sufficient direction or guidance to enable one of skill in the art to make a 1D3 monoclonal antibody which does **not** block anti-viral activity of ***any second Type I interferon*** (claim 21), because, as disclosed in Diaz, et al. (Biotherapy. 1996;8(3-4):157-62) and Roberts et al. (Prog Nucleic Acid Res Mol Biol. 1997;56:287-325)(see entire documents), the Type I interferon family of proteins is large and diverse across many mammalian species, and the instant specification does not provide sufficient guidance or direction for one of skill in the art to identify and/or isolate all of the Type I interferon ligands from diverse species and their cognate IFNAR2 receptor, and then design experimental systems to screen the anti-viral activity associated with the interaction of these ligand-receptor pairs and determine which are **not blocked** by the 1D3 antibody.

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Thus, undue experimentation would be required to produce the claimed invention commensurate with the scope of the claims from the written disclosure alone. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. **Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention.

Claims 3 recites “a polypeptide comprising a portion of the antibody of claim 1 or 2”; however, there is insufficient written description in the specification as-filed of the genus of polypeptides “comprising a portion of the antibody of claim 1 or 2” as recited in the instant claims.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3<sup>rd</sup> column). A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

The claim recites the genus polypeptides “comprising a portion of the antibody of claim 1 or 2” but does not recite a physical structure or testable functional activity for the “polypeptide comprising a portion of the antibody of claim 1 or 2”.

The genus of polypeptides “comprising a portion of the antibody of claim 1 or 2” is therefore extremely large. Applicant has disclosed only anti-IFNAR2 antibodies (see instant specification, pages 68-71). Thus Applicant has disclosed only a limited species of the polypeptides “comprising a portion of the antibody of claim 1 or 2”, namely anti-IFNAR2 antibodies. The claimed polypeptides “comprising a portion of the antibody of claim 1 or 2” lack a common structure essential for their function and the claims do not require any particular structure basis or testable functions be shared by the instant polypeptides “comprising a portion of the antibody of claim 1 or 2”.

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It does not appear based upon the limited disclosure of anti-IFNAR2 antibodies alone that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of polypeptides "comprising a portion of the antibody of claim 1 or 2".

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997).

The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406.

In the absence of disclosure of relevant, identifying characteristics of the polypeptides "comprising a portion of the antibody of claim 1 or 2" there is insufficient written disclosure under 35 U.S.C. 112, first paragraph.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

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11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 1-2, 5-8 and 15-23 are rejected under 35 U.S.C. 102(b)** as being anticipated by Chuntharapai et al. (FASEB Journal, abstract #1877, 10(6):A1325, April 30, 1996)(see entire document) as evidenced by the instant specification at pages 69-71 as well as Chuntharapai et al. (J Immunol. 1999 Jul 15;163(2):766-73)(see entire document)(citations C7 and C5, respectively, on applicants' substitute 1449A submitted January 13, 2003).

Chuntharapai teaches the creation of anti-IFNAR2 monoclonal antibodies 1D3, 1F3 and 3B7 by immunizing mice with IFNAR2-IgG (referred to as an IFN $\alpha$ A/D ELISA by Chuntharapai), and teaches that monoclonal antibody 1D3 does not block IFN $\alpha$ -1/2 binding or the anti-viral activity of various interferons, while 1F3 and 3B7 block all these activities.

The 1D3, 1F3 and 3B7 monoclonal antibodies described by Chuntharapai *inherently* have the biological activities recited in the instant claims as evidenced by the instant specification at pages 69-71 as well as Chuntharapai et al. (J Immunol. 1999, citation C5, see entire document).

Given the Chuntharapai abstract #1877 publication, one of skill in the art would be fully enabled to make an anti-IFNAR2 antibody that competes for binding to IFNAR2 with the 1D3, 1F3 and 3B7 monoclonal antibodies.

Moreover, given no assurances by one in position to collaborate the fact that the hybridomas which produce the 1D3, 1F3 and 3B7 monoclonal antibodies were not made available to the participants of the conference which was the basis for the Chuntharapai abstract publication of October 6, 1997, or the general public (in the absence of a signed confidentiality agreement), before October 6, 1997, the effective filing date of the instant application, it is assumed for the purposes of this rejection that the Chuntharapai abstract publication enabled one of skill in the art to also make the 1D3, 1F3 and 3B7 anti-IFNAR2 antibodies made by the particular hybridoma cell lines recited in claim 1.

Thus, Chuntharapai et al. anticipates the instant claims.

13. **Claims 2, 16, 18, 19 and 20 are rejected under 35 U.S.C. 102(b)** as being anticipated by Novick et al. (Cell. 1994 May 6;77(3):391-400)(see entire document), as evidenced by the instant specification at pages 69-71 as well as Chuntharapai et al. (J Immunol. 1999 Jul 15;163(2):766-73)(see entire document)(citations C30 and C5, respectively, on applicants' substitute 1449A submitted January 13, 2003).

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Novick teaches an anti-IFNAR2 antibody, for example anti-p40 antiserum, wherein the anti-p40 antiserum of Novick recognizes the IFNAR2, i.e., “anti-p40” is the same as “anti-IFNAR2” (see Results pages 392-396, in particular, page 394, right column, 1<sup>st</sup> paragraph to page 396). The anti-IFNAR2 antibody of Novick “completely blocks the anti-viral activity of natural and recombinant IFN- $\alpha$  subtypes...as well as IFN- $\beta$ ”. (see Results pages 392-396, in particular, page 393, left column and Figure 3).

Given that the anti-IFNAR2 antiserum of Novick binds IFNAR2, and blocks the anti-viral activity of natural and recombinant IFN- $\alpha$  subtypes and IFN- $\beta$ , as do the instantly claimed antibodies, as evidenced by the instant specification at pages 69-71 as well as Chuntharapai et al., see entire document, in particular Results pages 768-772, the anti-IFNAR2 antiserum of Novick will inherently compete for binding with the instantly claimed anti-IFNAR2 antibodies.

Since the Office does not have a laboratory to test the anti-IFNAR2 antiserum of Novick, it is applicant's burden to show that the reference antibodies do not compete for binding to IFNAR2 with the 1F3, 3B7 or 1D3 antibodies. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

14. **Claims 2, 16, 18, 19 and 20 are rejected under 35 U.S.C. 102(b)** as being anticipated by Colamonici et al. (J Biol Chem. 1993 May 25;268(15):10895-9)(see entire document), as evidenced by the instant specification at pages 2 and 69-71 as well as Chuntharapai et al. (J Immunol. 1999 Jul 15;163(2):766-73)(see entire document)(citations C13 and C5, respectively, on applicants' substitute 1449A submitted January 13, 2003).

Colamonici teaches an anti-IFNAR2 antibody, for example the IFN $\alpha$ R $\beta$ 1 monoclonal antibody (“IFN $\alpha$ R $\beta$ 1” is the same as “IFNAR2” as evidenced by the instant specification at page 2, 4<sup>th</sup> paragraph), that blocks the biological activities, including the binding activity, of various Type I IFN- $\alpha$  subtypes, see Results pages 10896-10897.

Given that the anti-IFNAR2 antibody of Colamonici blocks the biological activities, including the binding activity, of various Type I IFN- $\alpha$  subtypes, and given that the instantly claimed antibodies also block the biological activities, including the binding activity, of various Type I IFN- $\alpha$  subtypes, as evidenced by the instant specification at pages 69-71 as well as Chuntharapai et al., see entire document, in particular Results pages 768-772, the anti-IFNAR2 antibody of Colamonici will inherently compete for binding with the instantly claimed anti-IFNAR2 antibodies.

Since the Office does not have a laboratory to test the anti-IFNAR2 antibody of Colamonici, it is applicant's burden to show that the reference antibody does not compete for binding to IFNAR2 with the 1F3, 3B7 or 1D3 antibodies. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

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15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claims 1-3, 5-8 and 15-23 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Chuntharapai et al. (FASEB Journal, abstract #1877, 10(6):A1325, April 30, 1996)(see entire document), in view of Novick et al. (U.S. Patent No. 6,458,932)(see entire document).

The teachings of Chuntharapai are set forth above in section 12.

Chuntharapai does not teach anti-IFNAR2 antibody antigen binding fragments of claim 3.

Novick '932 teaches anti-IFNAR2 antibody antigen binding fragments, for example anti-IFNAB-BPI antibody antigen binding fragments, where "IFNAB-BPI" (which corresponds to SEQ ID NO: 2 of Novick '932) comprises residues 1-216 of SEQ ID NO: 26 from the instant application, which is the polypeptide that the 1F3, 3B7 and 1D3 monoclonal antibodies recognize (see Novick '932, in particular columns 13-15, the attached alignment and the "Supplemental Content Tab" under the "Image File Wrapper" tab for the instant application on public PAIR).

Novick '932 further teaches, "there are pathological situations in which the neutralization of IFN- $\alpha$  activity may be beneficial to the patient" and exemplifies the creation and characterization of an anti-IFNAR2 blocking antibodies (see, Novick '932, in particular column 2, 1<sup>st</sup> paragraph and Example 14, bridging columns 25-26).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the teaching of Chuntharapai with Novick '932 to practice the claimed invention because, Chuntharapai teach anti-IFNAR2 antibodies that compete with the instantly claimed antibodies (as described in section 12 above), and Novick '932 teaches anti-IFNAR2 antibody antigen binding fragments and that neutralizing antibodies, for example the antibodies of Chuntharapai which compete with the antibodies of the instant claims, are medically useful.

Given the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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17. **Claims 2, 3, 16, 18, 19 and 20 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Novick et al. (Cell. 1994 May 6;77(3):391-400)(see entire document) **OR** Colamonici et al. (J Biol Chem. 1993 May 25;268(15):10895-9)(see entire document), either in view of Novick et al. (U.S. Patent No. 6,458,932)(see entire document).

The teachings of Novick and Colamonici are set forth above in sections 13-14 above.

Novick and Colamonici do not teach anti-IFNAR2 antibody antigen binding fragments of claim 3,

Novick '932 teaches anti-IFNAR2 antibody antigen binding fragments, for example anti-IFNAB-BPI antibody antigen binding fragments, where "IFNAB-BPI" (which corresponds to SEQ ID NO: 2 of Novick '932) comprises residues 1-216 of SEQ ID NO: 26 from the instant application, which is the polypeptide that the 1F3, 3B7 and 1D3 monoclonal antibodies recognize (see Novick '932, in particular columns 13-15 and the attached alignment).

Novick '932 further teaches, "there are pathological situations in which the neutralization of IFN- $\alpha$  activity may be beneficial to the patient" and exemplifies the creation and characterization of an anti-IFNAR2 blocking antibodies (see, Novick '932, in particular column 2, 1<sup>st</sup> paragraph and Example 14, bridging columns 25-26).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the teaching of Novick OR Colamonici with Novick '932 to practice the claimed invention because, Novick OR Colamonici teach anti-IFNAR2 antibodies that compete with the instantly claimed antibodies (as described in sections 13-14 above), and Novick '932 teaches anti-IFNAR2 antibody antigen binding fragments and that neutralizing antibodies, for example the antibodies of Chuntharapai which compete with the antibodies of the instant claims, are medically useful.

Given the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.  
Patent Examiner  
August 16, 2006



PHILLIP GAMBEL, PH.D JD  
PRIMARY EXAMINER

TC 1600

8/17/06

3 pg. Alignment Attached

Z.S. 8/16/06